CDER GUIDANCES

NEW/REVISED/WITHDRAWN

1/1/2014 – 9/31/2014

(Sorted by date)

Title	Subject	Level at Date of Issue	Publication/ Withdrawal Date	Status
Qualification Process for Drug Development Tools	Procedural/Clinical Medical	Level 1	1/7/2014	New
Pulmonary Disease Tool for Measurement of Symptoms of Acute Bacterial Exacerbation of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease	Procedural/Clinical Medical Draft	Level 1	1/10/2014	New
Community-Acquired Pneumonia — Developing Antimicrobial Drugs for Treatment	Clinical/Anitmicrobial Draft	Level 1	1/10/2014	Revised
Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics	Advertising Draft	Level 1	1/14/2014	New
Dear Health Care Provider Letters:Improving Communication of Important Safety Information	Procedural	Level 1	1/23/2014	New
Providing Submissions in Electronic Format -- Standardized Study Data	Electronic Submissions Draft	Level 1	2/6/2014	Revised
Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act	Electronic Submissions Draft	Level 1	2/6/2014	New
Analgesic Indications: Developing Drug and Biological Products	Clinical/Medical Draft	Level 1	2/6/2014	New
Providing Regulatory Submissions in Electronic Format-- Receipt Date	Electronic Submissions	Level 1	2/7/2014	New
Analytical Procedures and Methods Validation for Drugs and Biologics	Chemistry, Manufacturing and Controls (CMC) Draft	Level 1	2/19/2014	New
New Chemical Entity Exclusivity Determinations for Certain Fixed-Combination Drug Products	Procedural Draft	Level 1	2/24/2014	New
E2B(R3) Electronic Transmission of Individual Case Safety Reports Implementa tion Guide — Data Elements and Message Specification; and Appendix to the Implementation Guide — Backwards and Forwards Compatibility10	ICH Efficacy Draft	Level 1	2/24/2014	Revised
Antiviral Product Development - Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HIV-1 Resistance Data: Attachment to the Guidance	Clinical/Anitmicrobial Draft	Level 1	2/28/2014	New
Distributing Scientific and Medical Publications on Unapproved New Uses — Recommended Practices - Revised Guidance	Procedural Draft	Level 1	3/3/2014	Revised
CMC Postapproval Manufacturing Changes To Be Documented in Annual Reports	Chemistry, Manufacturing and Controls (CMC)	Level 1	3/5/2014	New

Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Developing Drug Products for Treatment	Clincial/Medical Draft	Level 1	3/11/2014	New
Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products	Chemistry, Manufacturing and Controls (CMC) Draft	Level 1	3/14/2014	New
Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs — General Considerations	Biopharmaceutics Draft	Level 1	3/18/2014	New
Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway	Labeling Draft	Level 1	3/25/2014	New
Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act	Procedural Draft	Level 1	4/1/2014	New
Immunogenicity-Related Considerations for the Approval of Low Molecular Weight Heparin for NDAs and ANDAs	Chemistry, Manufacturing and Controls (CMC) Draft	Level 1	4/9/2014	New
Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations	Chemistry, Manufacturing and Controls (CMC)	Level 1	4/23/2014	New
Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment	Clinical/Anitmicrobial Draft	Level 1	5/7/2014	Revised
Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product	Biosimilarity Draft	Level 1	5/14/2014	New
ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers	Generic	Level 1	5/15/2014	New
Best Practices in Developing Proprietary Names	Drug Safety Draft	Level 1	5/29/2014	New
Expedited Programs for Serious Conditions--Drugs and Biologics	Procedural	Level 1	5/30/2014	New
Product Development Under the Animal Rule	Animal Rule Draft	Level 1	6/3/2014	New
Providing Submissions in Electronic Format — Postmarketing Safety Reports	Electronic Submission Draft	Level 1	6/10/2014	New
Distributing Scientific and Medical Publications on Risk Information for Approved Prescription Drugs and Biological Products—Recommended Practices	Procedural Draft	Level 1	6/11/2014	New
Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification	Procedural Draft	Level 1	6/11/2014	New
Abbreviated New Drug Application Submissions; Content and Format of Abbreviated New Drug Applications	Generics Draft	Level 1	6/12/2014	New
International Conference on Harmonisation; Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex 6 on Uniformity of Dosage Units General Chapter	ICH Quality Draft	Level 1	6/16/2014	New

Internet/Social Media Platforms With Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices	Advertising Draft	Level 1	6/18/2014	New
Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices	Advertising Draft	Level 1	6/18/2014	New
Uncomplicated Gonorrhea: Developing Drugs for Treatment	Clinical/Antimicrobial Draft	Level 1	6/19/2014	New
Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act	Procedural	Level 1	7/1/2014	New
Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act	Current Good Manufacturing Practices (CGMP) Draft	Level 1	7/1/2014	New
Neglected Tropical Diseases of the Developing World: Developing Drugs for Treatment or Prevention	Clinical/Antimicrobial	Level 1	7/3/2014	New
ANDA Submissions – Amendments and Easily Correctable Deficiencies Under GDUFA	Generics Draft	Level 1	7/10/2014	New
ANDA Submissions – Prior Approval Supplements Under GDUFA	Generics Draft	Level 1	7/10/2014	New
Reporting Drug Sample Information Under Section 6004 of the Affordable Care Act	Electronic Submissions Draft	Level 1	7/10/2014	New
Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications	Electronic Submissions Draft	Level 1	7/25/2014	Revised
Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the Public Health Service Act	Procedural/Biosimilarity Draft	Level 1	8/4/2014	New
Upper Facial Lines: Developing Botulinum Toxin Drug Products	Clinical/Medical Draft	Level 1	8/5/2014	New
Immunogenicity Assessment for Therapeutic Protein Products	Clinical/Medical; Chemistry, Manufacturing and Controls (CMC)	Level 1	8/13/2014	New
Clinical Pharmacology Labeling for Human Prescription Drug and Biological Products —Considerations, Content and Format	Labeling Draft	Level 1	8/13/2014	Revised
Controlled Correspondence Related to Generic Drug Development	Generics Draft	Level 1	8/26/2014	New
Electronic Submission of Lot Distribution Reports	CBER Draft	Level 1	Aug-14	New
ANDA Submissions — Refuse to Receive for Lack of Proper Justification of Impurity Limits	Generics Draft	Level 1	9/16/2014	New
ANDA Submissions -- Refuse-to-Receive Standards	Generics	Level 1	9/16/2014	New